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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,871	06/22/2001	Varouj Amirkhanian	1031/204	8028

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	13

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,871	AMIRKHANIAN, VAROUJ	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- Th MAILING DATE of this communication appears on th cov r sh et with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of the claims

The Request for Continued Examination and the amendment filed on September 15, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31, part (a) "having a second width larger than the first width" is vague and indefinite. It is unclear if "the first width" is referring to the first width of the separation channel or if it is referring to a first width of the detection section. It is unclear if the detection section has a second width larger than a first width of the detection section or if the width of the detection section is larger than the width of the separation channel.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-5, 7, 25-27, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (Axial-Beam Laser-Excited Fluorescence Detection in Capillary Electrophoresis, Anal. Chem. 1992, Vol. 64, 1741-1744) in view of Yin et al (US 5,650,846).

Taylor et al disclose a detection system for axial-beam laser excited fluorescence detection in capillary electrophoresis. Taylor et al disclose the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). Taylor et al also disclose that this fiber is directed into an end of the detection section in proximity to the detection zone (col 1, page 1742, lines 8-10). Taylor et al also disclose the use of cladding material and a jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone (col 2, page 1741, lines 12-18). Taylor et al also disclose a means for detecting radiation emission from the detection zone (col 1, page 1742, lines 22-39).

Taylor et al differs from the instant invention in failing to teach the separation channel having a first width, and the detection zone having a second width larger than the first width.

Yin et al disclose a microcolumnar separation device (col 4, lines 20-67). Yin et al disclose that this microcolumn separation device can be a capillary electrophoresis

channel (separation channel) (col 4). Yin et al disclose that the separation channel comprises a detection zone (Fig. 8, items 18, 124 139, 130 and 128, the detection region extends from item 18 to item 130). Yin et al disclose that the separation channel comprises a flare located at the end of the separation channel (col 7, line 48 – column 8, line 9). Yin et al disclose that detection zone has an enlarged opening to the lumen of the separation channel for receiving the optical fiber. Yin et al disclose that detection zone provides the alignment and nonfixed confinement of optical fiber to the separation channel.

It would have been obvious to one of ordinary skill in the art to incorporate a detection zone as taught by Yin et al into the device of Taylor et al because Yin et al shows that this detection zone provides the alignment and nonfixed confinement of optical fiber to the microcolumn.

4. Claims 1-5, 7, 25-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (Axial-Beam Laser-Excited Fluorescence Detection in Capillary Electrophoresis, Anal. Chem. 1992, Vol. 64, 1741-1744) in view of Zhu et al (US 5,763,277).

Taylor et al disclose a detection system for axial-beam laser excited fluorescence detection in capillary electrophoresis. Taylor et al disclose the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). Taylor et al also disclose that this fiber is directed into an end of the detection section in proximity to the detection zone (col 1, page 1742, lines 8-10). Taylor et al also disclose the use of cladding material and a

jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone (col 2, page 1741, lines 12-18). Taylor et al also disclose a means for detecting radiation emission from the detection zone (col 1, page 1742, lines 22-39).

Taylor et al differs from the instant invention in failing to teach the separation channel having a first width, and the detection zone having a second width larger than the first width.

Zhu et al disclose a detection system which comprises a capillary tube (col 6, line 46) used for electrophoresis (separation channel) (col 2, lines 49-51) which defines a detection zone. Zhu et al also disclose that the inner diameter of the axially oriented system component is increased at the location of contained axially oriented fiber optic means (col 5, lines 1-3). Zhu et al disclose that the increased diameter provides a non-constricted annular space in which sample analyte containing sample solution can flow, in the presence of the fiber optic (col 6, lines 15-21).

It would have been obvious to one of ordinary skill in the art to incorporate a separation channel and detection zone has taught by Zhu et al into the device of Taylor et al because Zhu et al shows that this separation channel and detection zone provides a non-constricted annular space in which sample analyte containing sample solution can flow, in the presence of the fiber optic.

5. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al as applied to claims 1-5, 7, 25-27 and 29-31 above and further in view of Liu et al (US 5,416,879).

See above for teachings of Taylor et al and Zhu et al.

Taylor et al Zhu et al differ from the instant invention in failing to teach the tube is made of Teflon and the light transmitting material comprises a gel.

Liu et al disclose Teflon fluoropolymer capillary tubing which has a refractive index in the range of approximately 1.29 to 1.31 (col 4, lines 18-21). This Teflon tubing allows for the channeling light through a light conducting core region which is surrounded or clad by the Teflon fluoropolymer which has a lower refractive index to the light than the material comprising the core and thus allows the propagation of light with negligible losses through an optical fiber (col 3, lines 50-55).

It would have been obvious to one of ordinary skill in the art to incorporate the use of the Teflon fluoropolymer as taught by Liu et al into the modified detection system of Taylor et al because Liu et al shows that this Teflon tubing allows for the channeling of light through a light conducting core region which is surrounded or clad by the Teflon fluoropolymer which has a lower refractive index to the light than the material comprising the core and thus allows the propagation of light with negligible losses through an optical fiber.

With respect to the light transmitting material comprising a gel Taylor et al teaches the insertion of the fiber (light transmitting material) into the separation channel (comprised of the gel), thus the light transmitting material comprises a gel.

6. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al as applied to claims 1-5, 7, 25-27 and 29-31 above, and further in view of Hazman et al (US 5,625,403).

See above for teachings of Taylor et al and Zhu et al.

Taylor et al and Zhu et al differ from the instant invention in failing to teach introducing excitation radiation from at least two radiation sources providing radiation at different wavelengths. Taylor et al and Zhu et al also fail to teach the use of a beam splitter.

Hazman et al disclose the use of multiple diode lasers (radiation sources), each of which emits a source beam of light of different wavelengths (see abstract). Hazman et al also disclose an optical element that channels the radiation from the different radiation sources. Hazman et al also disclose the use of a beam splitter (see figure 2). The use of the radiation sources, optical element and beam splitter provides a method of recording on an optically-sensitive medium and enables the realization of a practical high power optical head (col 2, lines 27-36).

It would have been obvious to one of ordinary skill in the art to incorporate the use of radiation sources, an optical element and a beam splitter as taught by Hazman et al into the modified detection system of Taylor et al because Hazman et al shows that the use of the radiation sources, optical element and beam splitter provides a method of recording on an optically-sensitive medium and enables the realization of a practical high power optical head

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. in view of Zhu et al and Hazman et al as applied to claims 1-5, 7, 9-14, 25-27 and 29-31 above, and further in view of Amirkhanian et al (US 6,184,990).

See above for teachings of Taylor et al., Zhu et al. and Hazman et al.

Taylor et al., Zhu et al., and Hazman et al differ from the instant invention in failing to disclose a means of introducing excitation radiation comprising two fibers directed at the detection zone, wherein each fiber is coupled to one radiation source.

Amirkhanian et al disclose the use of two optical fibers that are utilized for delivery of the excitation from two or more different sources. This arrangement enables multiple fluorescence species in the same sample to be excited at the same time for simultaneous detection.

It would have been obvious to one of ordinary skill in the art to incorporate the use of two optical fibers as taught by Amirkhanian et al into the modified detection system of Taylor et al because Amirkhanian et al shows that this arrangement enables multiple fluorescence species in the same sample to be excited at the same time for simultaneous detection.

8. Claims 16-18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Yin et al as applied to claims 1-5, 7, 25-27 and 29-31 above, and further in view of Letcher et al (US 6,326,213) or Liu et al (US 5,444,807).

See above for teachings of Taylor et al and Yin et al.

Taylor et al and Yin et al differ from the instant invention in failing to teach the means for axially detecting radiation emission shares the same single fiber as the means for introducing excitation radiation axially to transmit excitation radiation and radiation emission.

Letcher et al disclose a single step-tapered fiber used for excitation and detection (col 3, lines 1 and 2, see also abstract). The use of this fiber allows for

enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of an analyte.

Liu et al (US 5,444,807) disclose a single fiber optic for both axial light input to and output from flow through detectors (abstract and col 6, lines 44-60). Liu et al disclose that this provides for a novel technique by which light absorption and fluorescence may be used as measures of properties of small amounts of a flowing fluid analyte, particularly in conjunction with liquid chromatography and capillary electrophoresis (col 4, lines 36-50).

It would have been obvious to one of ordinary skill in the art to incorporate the fiber of Letcher et al into the modified detection system of Taylor et al because Letcher et al shows that the use of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of an analyte.

It also would have been obvious to one of ordinary skill in the art to incorporate the fiber optic of Liu et al into the modified detection system of Taylor et al because Liu et al shows that this provides for a novel technique by which light absorption and fluorescence may be used as measures of properties of small amounts of a flowing fluid analyte, particularly in conjunction with liquid chromatography and capillary electrophoresis.

9. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Yin et al and Liu et al (US 5,444,807) as applied to claims 1-5, 7, 16-18, and 25-31 above, and further in view of Hazman et al (US 5,625,403).

See above for teachings of Taylor et al., Yin et al., and Liu et al.

Taylor et al., Yin et al., and Liu et al differ from the instant invention in failing to disclose a confocal optical element that transmits excitation radiation and radiation emission.

Hazman et al disclose the use of a dichroic beam combiner along with a set of lens. This dichroic beam combiner is used to selectively reflect and transmit light according to its wavelength (col 4, lines 30-33). The use of the beam combiner and set of lens allows for the combination of laser beams and enabling the realization of a practical high power optical head.

It would have been obvious to one or ordinary skill in the art to incorporate the beam combiner and set of lens as taught by Hazman et al into the modified detection system of Taylor et al because Hazman et al shows that the use of the beam combiner allows for selectivity of light reflection and transmission according to its wavelength and the beam combiner and set of lens also allows for the combination of laser beams and enabling the realization of a practical high power optical head.

10. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al as applied to claims 1-5, 7, 25-27 and 29-31 above, and further in view of Pentoney, Jr. et al (US 5,675,155).

See above for teachings of Taylor et al and Zhu et al.

Taylor et al and Zhu et al differ from the instant invention in failing to teach the use of a parabolic reflective collector.

Pentoney, Jr. et al disclose the use of a high collection efficiency parabolic reflector (col 5, lines 14-39). The use of this parabolic reflector allows for an economical highly sensitive, stable and rugged detection system for use in connection with high throughput separation systems and also allows for multiple excitation wavelengths and detecting multiple emission wavelengths using a single detector (col 2, lines 24-32).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a parabolic reflector as taught by Pentoney, Jr. et al into the modified detection system of Taylor et al because Pentoney, Jr. et al shows that the use of this parabolic reflector allows for an economical highly sensitive, stable and rugged detection system for use in connection with high throughput separation systems and also allows for multiple excitation wavelengths and detecting multiple emission wavelengths using a single detector.

Response to Arguments

11. Applicant's arguments with respect to claim1-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zhu et al (US 6,008,055) disclose systems and methods for inducing and detecting sample analyte(s) and identifying fluorescence.

Peterson (US 4,792,689) discloses a single fiber optic for input and output of light.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art unit 1641
November 7, 2003

LONG V. LE
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11/6/03